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(Modified)

U.S. Department of Commerce Patent and Trademark Office

Attorney Docket No.: OPHD-02304

Serial No.:

Applicant: James A. Williams et al.

TION DISCLOSURE STATEMENT BY APPLICANT s If Necessary) Group Art Unit: 1816 Filing Date: (37 CFR § 1.98(b)) ADEMA U.S. PATENT DOCUMENTS Filing Date Subclass Serial / Patent Class Applicant / Patentee Examiner Issue Date Number Initials Tokoro 1/14/92 5,080,895 OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication) Cato et al. (1986) "Clostridium," in Bergey's Manual® of Systematic Bacteriology, 2:1141-1200, Sneath (ed.), Williams & Wilkins 2 Engelkirk et al. (1992) "Classification," in Principles and Practice of Clinical Anaerobic Bacteriology, pp. 22-23, Star Publishing Co., 3 Belmont, CA Stephen and Pietrowski (1986) "Toxins Which Traverse Membranes and Deregulate Cells," in Bacterial Toxins, 2d ed., pp. 66-67, American 4 Society for Microbiology Berkow and Fletcher (eds.) (1992) "Bacterial Diseases," in Merck Manual of Diagnosis and Therapy, 16th ed., pp. 116-126, Merck Research 5 Laboratories, Rahway, N.J. Sigmund and Fraser (eds.) (1979) "Clostridial Infections," in Merck Veterinary Manual, 5th ed., pp. 396-409, Merck & Co., Rahway, N.J. 6 Hatheway (1990) "Bacteriophages and plasmids and their roles in coding for botulinal neurotoxins," Clin. Microbiol. Rev. 3:73-74 7 Arnon (1986) "Infant Botulism: Anticipating the Second Decade," J. Infect. Dis. 154:201-206 8 Arnon (1980) "Infant Botulism," Ann. Rev. Med. 31:541-559 9 MacDonald et al. (1986) "The Changing Epidemiology of Adult Botulism in the United States," Am. J. Epidemiol. 124:794-799 10 Tacket et al. (1984) "Equine Antitoxin Use and Other Factors That Predict Outcome in Type A Foodborne Botulism," Am. J. Med. 76:794-11 798 Swartz (1990) "Anaerobic Spore-Forming Bacilli: The Clostridia," in B.D. Microbiology, 4th edition, pp. 633-646, Davis et al.(eds.), J.B. 12 Lippincott Co. Holzer (1962) "Botulismus durch Inhalation," Med. Klin. 41:1735-738 13 Franz et al. (1993) in Botulinum and Tetanus Neurotoxins, pp. 473-476, B.R. DasGupta, ed., Plenum Press, NY 14 Arnon et al. (1981) "Infant Botulism: Epidemiology and Relation to Sudden Infant Death Syndrome," Epidemiol. Rev. 3:45-66 15 Frankovich and Arnon (1991) "Clinical Trial of Botulism Immune Globulin for Infant Botulism," West. J. Med. 154:103 16 Sugiyama (1980) "Clostridium botulinum Neurotoxin," Microbiol. Rev. 44:419-448 17 Balady (1991) "Botulism Antitoxin Fielded for Operation Desert Storm," USAMRDC Newsletter, p. 6 18 Schwarz and Arnon (1992) "Botulism Immune Globulin for Infant Botulism Arrives-One Year and A Gulf War Later," Western J. Med. 19 156:197-198 Peterson et al. (1979) "The Sudden Infant Death Syndrome and Infant Botulism," Rev. Infect. Dis. 1:630-634 20 Arnon et al. (1978) "Intestinal Infection and Toxin Production by Clostridium Botulinum as One Cause of Sudden Infant Death Syndrome," 21 Lancet, pp. 1273-1277 Informational Brochure for the Pentavalent (ABCDE) Botulinum Toxoid, Centers for Disease Control, Rev. 1995, pp. 1-3 and 3 22 unnumbered pages Brooks et al. (eds.) (1991) "Infections Caused by Anaerobic Bacteria," in Jawetz, Melnick, & Adelberg's Medical Microbiology, 19th ed., pp. 257-262, Appleton & Lange, San Mateo, CA 23 Engelkirk et al. (1992) Principles and Practice of Clinical Anaerobic Bacteriology, pp. 64-67, Star Publishing Co., Belmont, CA 24 Lyerly et al. (1992) "Characterization of a Toxin A-Negative, Toxin B-Positive Strain of Clostridium difficile," Infect. Immun. 60:4633-4639 25 Borriello et al. (1990) "Virulence Factors of Clostridium difficile," Rev. Infect. Dis., 12(Suppl. 2):S185-S191 26 Lyerly et al. (1985) "Effects of Clostridium difficile Toxins Given Intragastrically to Animals," Infect. Immun. 47:349-352 27 Date Considered: Examiner:

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